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Attorney Docket No. 23164-1001

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Amendment

Application No. 08/853,870

OCT 28 1998

GROUP 1600

Please add the following claims:

21. (New) The method of claim 6, <sup>1</sup> said amount of an interferon being greater than about  $20 \times 10^6$  IU of interferon for a 70 kg human. <sup>1</sup> B

22. (New) The method of claim 6, in which the effective dose of interferon is administered in a single dose. <sup>1</sup> 3

23. (New) The method of claim 6, in which the effective dose of interferon is administered in a plurality of smaller doses over a period of time sufficient to elicit a response equivalent to that of a single dose. <sup>1</sup> 4

24. (New) The method of claim 6, in which an effective dose of interferon is administered continuously over a period of time sufficient to elicit a response equivalent to that of a single dose. <sup>1</sup> 5

25. (New) The method of claim 6, wherein the interferon comprises a Type I interferon. <sup>1</sup> 6

26. (New) The method of claim 25, wherein the interferon is selected from the group consisting of IFN- $\alpha$ , IFN- $\beta$ , IFN- $\omega$ , consensus IFN, and mixtures thereof. <sup>1</sup> 7

27. (New) The method of claim 26, wherein the IFN- $\alpha$  comprises recombinant IFN- $\alpha$ . <sup>1</sup> 8

28. (New) The method of claim 6, wherein the interferon comprises a Type II interferon. <sup>1</sup> 9

29. (New) The method of claim 28, wherein the Type II interferon comprises IFN- $\gamma$ . <sup>1</sup> 10

30. (New) The method of claim 6, wherein the dose of interferon is <sup>greater than</sup> ~~from about~~  $20 \times 10^6$  IU to about  $1000 \times 10^6$  IU of interferon. <sup>1</sup> 11

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c 31. (New) The method of claim 6, wherein the dose of interferon is <sup>greater than</sup> from about  $20 \times 10^6$  IU to about  $500 \times 10^6$  IU of interferon.

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conty 32. (New) The method of claim 6, wherein the dose of interferon is from about  $50 \times 10^6$  IU to about  $500 \times 10^6$  IU of interferon.

c 33. (New) The method of claim 6, wherein the neoplastic <sup>condition</sup> disease is selected from the group consisting of renal cell carcinoma, bladder cancer, cervical cancer, malignant melanoma, multiple myeloma, Kaposi's sarcoma, hairy cell leukemia, non-Hodgkin's lymphoma, chronic myeloid leukemia, nasopharyngeal carcinoma, breast cancer, large bowel (colon) cancer, uterine cancer, head and neck cancers, glioblastoma, cutaneous T-cell lymphoma, basal cell carcinoma, brain tumors, and lung cancer.

# REMARKS

New Claims 21-32 depend from Claim 6 and contain limitations previously found in prior claims 1, 3-5, 7-12, and 14-16. Claim 33 further specifies neoplastic conditions for which the interferon is either approved for use or currently involved in efficacy studies. Support for Claim 33 can be found on pages 6-7.

## Rejection under 35 USC §103 of claims 17-20

Claims 17-20 stand rejected under 35 USC §103(a) as being unpatentable over Samo et al. Samo allegedly teaches a dose of  $40 \times 10^6$  units of interferon and, thus, provides the motivation to make the claimed composition. Applicants respectfully disagree.

The instant invention is directed to the oromucosal administration of an ultra-high dose for interferon treatment, free of adverse reactions, of a neoplastic disease. First, , Samo et al., by their own admission, administer "two relatively small doses" of interferon. See Abstract. Further, Applicants note